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114TH CONGRESS
1ST SESSION

H. R. 971

To amend the Federal Food, Drug, and Cosmetic Act to authorize a 6-month extension of certain exclusivity periods in the case of approved drugs that are subsequently approved for a new indication to prevent, diagnose, or treat a rare disease or condition, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 13, 2015

Mr. BILIRAKIS (for himself, Mr. MCCAUL, and Mr. BUTTERFIELD) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act to authorize a 6-month extension of certain exclusivity periods in the case of approved drugs that are subsequently approved for a new indication to prevent, diagnose, or treat a rare disease or condition, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Orphan Product Extensions Now Accelerating Cures and Treatments Act of 2015''.

SEC. 2. EXTENSION OF EXCLUSIVITY PERIODS FOR A DRUG APPROVED FOR A NEW INDICATION FOR A RARE DISEASE OR CONDITION.

(a) IN GENERAL.—Chapter V of the Federal Food, Drug, and Cosmetic Act is amended by inserting after section 505E of such Act (21 U.S.C. 355f) the following:

"SEC. 505F. EXTENSION OF EXCLUSIVITY PERIODS FOR A DRUG APPROVED FOR A NEW INDICATION FOR A RARE DISEASE OR CONDITION.

"(a) DESIGNATION.—

"(1) IN GENERAL.—The Secretary shall designate a drug as a drug approved for a new indication to prevent, diagnose, or treat a rare disease or condition for purposes of granting the extensions under subsection (b) if—

"(A) prior to approval of an application or supplemental application for the new indication, the drug was approved or licensed for marketing under section 505(c) of this Act or section 351(a) of the Public Health Service Act, but was not so approved or licensed for the new indication;

"(B) the sponsor of the approved or licensed drug files an application or a supplemental application for approval of the new indi-

cation for use of the drug to prevent, diagnose, or treat the rare disease or condition;

"(C) the application or supplemental application for the new indication contains—

"(i) a request for designation of the drug under this section;

"(ii) the consent of the applicant to notice being given by the Secretary under paragraph (4) respecting the designation of the drug; and

"(iii) in the case of a drug for which an extension is sought under subsection (b)(3), a list specifying each patent—

"(I) which claims the drug or a method of using the drug; and

"(II) with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug; and

"(D) the Secretary approves the application or supplemental application.

"(2) REVOCATION OF DESIGNATION.—

"(A) IN GENERAL.—Except as provided in subparagraph (B), a designation under this subsection shall not be revoked for any reason.

"(B) EXCEPTION.—The Secretary may revoke a designation of a drug under paragraph (1) if the Secretary finds that the application or supplemental application resulting in such designation contained an untrue statement of material fact.

"(3) NOTIFICATION PRIOR TO DISCONTINUANCE OF PRODUCTION FOR SOLELY COMMERCIAL REASONS.—A designation of a drug under paragraph (1) shall be subject to the condition that the sponsor of the drug will notify the Secretary of any discontinuance of the production of the drug for solely commercial reasons at least one year before such discontinuance.

"(4) NOTICE TO PUBLIC.—Notice respecting the designation of a drug under paragraph (1)—

"(A) shall be made available to the public; and

"(B) shall include any listing of patents under subsection (a)(1)(C)(iii).

''(b) EXTENSION.—If the Secretary designates a drug as a drug approved for a new indication for a rare disease or condition, as described in subsection (a)(1)—

''(1)(A)(i) the 4-, 5-, and 7½-year periods described in subsections (c)(3)(E)(ii) and (j)(5)(F)(ii) of section 505, and the 3-year periods described in clauses (iii) and (iv) of subsection (c)(3)(E) and clauses (iii) and (iv) of subsection (j)(5)(F) of section 505, as applicable, shall be extended by 6 months; or

''(ii) the 4- and 12-year periods described in subparagraphs (A) and (B) of section 351(k)(7) of the Public Health Service Act, as applicable, shall be extended by 6 months; and

''(B) the 7-year period described in section 527, as applicable, shall be extended by 6 months;

''(2) if, at the time a drug is designated under subsection (a)(1)—

''(A) the drug is the subject of a listed patent for which a certification has been submitted under subsection (b)(2)(A)(ii) or (j)(2)(A)(vii)(II) of section 505 or a listed patent for which a certification has been submitted under subsections (b)(2)(A)(iii) or (j)(2)(A)(vii)(III) of section 505, the period

during which an application may not be approved under section 505(c)(3) or section 505(j)(5)(B) shall be extended by a period of 6 months after the date the patent expires (including any patent extensions); or

''(B) the drug is the subject of a listed patent for which a certification has been submitted under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505, and in the patent infringement litigation resulting from the certification the court determines that the patent is valid and would be infringed, the period during which an application may not be approved under section 505(c)(3) or section 505(j)(5)(B) shall be extended by a period of 6 months after the date the patent expires (including any patent extensions); and

''(3) if the drug is a biological product, the Secretary shall not grant final effective approval for any application submitted under section 351(k)(1) of the Public Health Service Act for a biosimilar biological product that cites such drug as its reference product until the date that is 6 months after the expiration of every patent that, as of the date on which the drug is designated under subsection (a)(1), is listed

for such drug pursuant to subsection (a)(1)(C)(iii), except that, if a court from which no appeal (other than a writ of certiorari) has been or could be taken rules a listed patent invalid or not infringed, then such patent shall no longer be considered for purposes of this paragraph.

''(c) RELATION TO PEDIATRIC AND QUALIFIED INFECTIOUS DISEASE PRODUCT EXCLUSIVITY.—Any extension under subsection (b) of a period shall be in addition to any extension of the periods under sections 505A and 505E of this Act and section 351(m) of the Public Health Service Act, as applicable, with respect to the drug.

''(d) LIMITATIONS.—The extension described in subsection (b) shall not apply if the drug designated under subsection (a)(1) has previously received an extension by operation of subsection (b).

''(e) REGULATIONS.—

''(1) IN GENERAL.—Not later than 2 years after the date of enactment of this section, the Secretary shall adopt final regulations implementing this section.

''(2) PROCEDURE.—In promulgating a regulation implementing this section, the Secretary shall—

''(A) issue a notice of proposed rulemaking that includes the proposed regulation;

"(B) provide a period of not less than 60 days for comments on the proposed regulation; and

"(C) publish the final regulation not less than 30 days before the effective date of the regulation.

"(3) RESTRICTIONS.—Notwithstanding any other provision of law, the Secretary shall promulgate regulations implementing this section only as described in paragraph (2), except that the Secretary may issue interim guidance for sponsors seeking to submit an application or supplemental application described in subsection (a) prior to the promulgation of such regulations.

"(4) DESIGNATION PRIOR TO REGULATIONS.—The Secretary shall designate drugs under subsection (a) prior to the promulgation of regulations under this subsection, if such drugs meet the criteria described in subsection (a).

"(f) DEFINITION.—In this section:

"(1) The terms 'biological product', 'biosimilar', and 'reference product' have the meanings given to such terms in section 351(i) of the Public Health Service Act.

''(2) The term 'rare disease or condition' has the meaning given to such term in section 526(a)(2).''.

(b) APPLICATION.—Section 505F of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), applies only with respect to a drug for which an application or supplemental application described in subparagraphs (B) and (C) of subsection (a)(1) of such section 505F is first approved under section 505(c) of such Act (21 U.S.C. 355(c)) or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) on or after the date of the enactment of this Act.

(c) CONFORMING AMENDMENTS.—

(1) RELATION TO PEDIATRIC EXCLUSIVITY FOR DRUGS.—Section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) is amended—

(A) in subsection (b), by adding at the end the following:

''(3) RELATION TO EXCLUSIVITY FOR A DRUG APPROVED FOR A NEW INDICATION FOR A RARE DISEASE OR CONDITION.—Notwithstanding the references in subsection (b)(1) to the lengths of the exclusivity periods after application of pediatric exclusivity, the 6-month extensions described in sub-

section (b)(1) shall be in addition to any extensions under section 505F.''; and

(B) in subsection (c), by adding at the end the following:

''(3) RELATION TO EXCLUSIVITY FOR A DRUG APPROVED FOR A NEW INDICATION FOR A RARE DISEASE OR CONDITION.—Notwithstanding the references in subsection (c)(1) to the lengths of the exclusivity periods after application of pediatric exclusivity, the 6-month extensions described in subsection (c)(1) shall be in addition to any extensions under section 505F.''.

(2) RELATION TO EXCLUSIVITY FOR NEW QUALIFIED INFECTIOUS DISEASE PRODUCTS THAT ARE DRUGS.—Subsection (b) of section 505E of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355f) is amended—

(A) by amending the subsection heading to read as follows: ''RELATION TO PEDIATRIC EXCLUSIVITY AND EXCLUSIVITY FOR A DRUG APPROVED FOR A NEW INDICATION FOR A RARE DISEASE OR CONDITION''; and

(B) by striking ''any extension of the period under section 505A'' and inserting ''any

extension of the periods under sections 505A or 505F''.

(3) RELATION TO PEDIATRIC EXCLUSIVITY FOR BIOLOGICAL PRODUCTS.—Section 351(m) of the Public Health Service Act (42 U.S.C. 262(m)) is amended by adding at the end the following:

''(5) RELATION TO EXCLUSIVITY FOR A BIOLOGICAL PRODUCT APPROVED FOR A NEW INDICATION FOR A RARE DISEASE OR CONDITION.—Notwithstanding the references in paragraphs (2)(A), (2)(B), (3)(A), and (3)(B) to the lengths of the exclusivity periods after application of pediatric exclusivity, the 6-month extensions described in such paragraphs shall be in addition to any extensions under section 505F.''.

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